## REMARKS

**Status of the Claims.**

Claims 1-8 are pending with entry of this amendment, claims 9-10 being canceled and no claims being added herein. Claim 1 is amended herein. This amendment introduces no new matter. Support is replete throughout the specification. Support for example, for the fact that the very large family is a "subpopulation" of the database is found for example, at page 15, paragraph 0052 (example 1, wherein the very large family is about 500 to about 10,000 while the UPDB contains about 1.7 million individuals. Support for "linking step" is found on page 8 in paragraph 0033, and the like.

**Interview.**

Applicants thank the Examiner for the interview granted on 26 July 2007. Applicants note that the substance of the claims was discussed with respect to the disclosure in Palsson (US 6,524,797). No agreement was reached.

**Advisory action.**

In response to the Final Office Action dated April 18, 2007, an amendment after final was filed on August 18, 2007 with a petition for a three month extension of time. In an advisory action mailed on September 14, 2007, the Examiner refused entry of the amendment alleging that it raised new issues that would require further consideration and/or a search.

Accordingly, the amended claims are provided again herein along with a Request for Continued Examination (RCE).

Applicants note that the Examiner stated in the Advisory Action that the amendment ". . . appears to overcome the prior rejection of claims 1-8 under 35 U.S.C. §102 . . . ".

**35 U.S.C. §102.**

Claims 1-8 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Palsson (US 6,524,797) as evidenced by family search.org (1999). Applicants traverse.

The Examiner is respectfully reminded that in order to make a *prima facie* case of anticipation, **all limitations** of the claims must be found in the cited reference or "fully met by it". *Kalman v Kimberly-Clark Corp.*, 218 USPQ 781, 789 (Fed. Cir. 1983).

In the instant case, claim 1, as amended herein, is directed to:

Claim 1 (Currently amended): A method of determining statistical significance of disease incidence, said method comprising:

a) selecting at least one founder from a computerized genealogical database;

b) identifying a very large family from the founder in said computerized genealogical database**, wherein said very large family comprises a subpopulation of said genealogical database**;

c) linking the very large family to a disease database, **wherein said linking comprises determining an incidence of disease by calculating the number and distribution of disease cases within the very large family**;

d) **comparing the incidence of disease in the very large family to a general population incidence of disease**; and

e) **assessing a statistical significance of the disease incidence in the very large family** and **presenting a measure of said statistical significance on a display or printout**.

None of the elements underlined above are found in Palsson.

The Examiner alleges that Palsson teaches claim 1 at col. 3, lines 49-67, col. 4, lines 1-4 and lines 59-67, col. 5, lines 1-10 and 38-67, and col. 6, lines 1-39. The Examiner, however, fails to identify with particularity where each of the steps recited in claim 1 are to be found in Palsson.

More particularly, Palsson is directed to methods of identifying therapeutic compounds effective against pathological conditions by contacting **a cell** from a diseased individual and a cell from a healthy individual with the potential therapeutic compound(s).

The language cited by the Examiner at col. 3, line 49 through col. 4, line 4, simply defines a pathological condition, and teaches that the invention can be practiced with respect to monogenetic diseases such as those described in the Online Mendelian Inheritance in Man database.

The language cited by the Examiner at col. 4, line 59 through col. 5, line 10 simply teaches that the pharmaceutical screening method can be practiced using cells from multiple individuals from a large family or genetically homogeneous population including normal and diseased individuals. This section further teaches that the degree of relatedness of the individuals within the pedigree and the relative risk for each individual within the pedigree of exhibiting the disease can be established and the number of normal and diseased individuals can be determined.

At col. 5, lines 38-67, Palsson simply teaches that in obtaining cells from diseased and healthy individuals, the degree of severity of the pathology and the degree of risk of developing the pathological condition for each individual can be determined " . . . **using knowledge of the risk**

**factors**, pathological mechanisms, and clinical signs and symptoms of a given disease". (col. 5, lines 41-43). **However, no particular methods of identifying risk or significance of disease incidence are taught.**

The language cited by the Examiner at col. 5, line 38 through col. 6, line 39 simply teaches that the method [of identifying therapeutic compounds by screening cells] can be practiced using cells from individuals from genetically homogenous populations, and provides examples of genetically homogenous populations.

Palsson is directed to screening cells to identify therapeutic compounds. Palsson offers no specific teaching of "[a] method of determining statistical significance of disease incidence" as recited in the present claim.

Further, claim 1, as amended herein recites

> a) selecting **at least one founder** from a computerized genealogical database;
> b) identifying a very large family from the founder in said computerized genealogical database**, wherein said very large family comprises a subpopulation of said genealogical database**;

Palsson does not teach these steps. To the contrary, in the only reference to "founders" in the Palsson patent pertains to the description of genetically homogeneous populations:

> A method of the invention can advantageously be practiced using **cells from individuals from genetically homogeneous populations**, such as geographically isolated populations with relatively few founder individuals, or populations that are isolated for cultural or religious reasons. Isolated populations have had relatively little inward migration or intermarriage, and a result, **most of the population is descended from the original founder individuals**. [emphasis added] (col. 5, lines 52-58)
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> **Examples of genetically homogeneous populations** of individuals are known in the art and include, for example, geographically isolated populations, such as island populations. Preferably, genetically homogeneous populations of individuals have extensive and accurate medical records and detailed genealogical records. Genetically homogeneous populations with extensive medical and genealogical records are well known in the art and include, for example, the population of Iceland, populations of the

> Scandinavian countries, the **Mormon population of Utah,** . . . [emphasis added] (col. 6, lines 6-15)

Thus Palsson teaches the **entire** Mormon population of Utah as a genetically homogeneous population. Palsson offers no teaching regarding the identification of a very large family from the founder, where the very large family comprises **a subpopulation** of the genealogical database as recited in claim 1. .

Palsson also fails to teach:

> c) linking the very large family to a disease database, **wherein said linking comprises determining an incidence of disease by calculating the number and distribution of disease cases within the very large family.**

as recited in claim 1. Since Palsson fail to teach a very large family (VLF) that is a subpopulation of the genealogical database, this reference **cannot** teach calculating the number and distribution of disease cases within the very large family. Moreover, Palsson fails to teach the calculation of the number and distribution of any disease cases. Indeed, a search of the Palsson patent shows that the term "distribution" occurs nowhere in the document.

Because Palsson fails to teach a very large family (VLF) that is a subpopulation of the genealogical database, this reference **cannot** teach:

> d) comparing the incidence of disease in the very large family to a general population incidence of disease; and

as recited in claim 1. Moreover Palsson nowhere teaches comparing the incidence of disease within one population (*e.g.,* VLF) to a general population incidence of disease.

Indeed, if the Examiner's intent is to construe the Mormon population of Utah as a very large family, Palsson would have to teach comparison of the disease incidence in the Mormon population to the general population incidence of disease. Palsson offers no such teaching.

If the Examiner's intent is to construe the Mormon population of Utah as the general population, then Palsson offers no subset of that population (*i.e.,* VLF) for the comparison recited in step d. Thus Palsson clearly fails to teach a method comprising this step.

Because Palsson fails to teach a very large family (VLF) that is a subpopulation of the genealogical database, this reference **cannot** teach

> e) assessing a statistical significance of the disease incidence in the very large family and **presenting a measure of said statistical significance on a display or printout**.

as recited in claim 1. In addition, a search of Palsson shows that there is no reference whatsoever to presenting any data, on a display or printout.

Moreover, the only reference in Palsson to an "incidence of disease" is to note that certain populations exist that have an increased incidence of certain diseases:

> For certain diseases, epidemiological studies have been conducted among genetically homogeneous populations with an **increased incidence of the disease**. Therefore, a method of the invention can be practiced using cells obtained from diseased and normal individuals within such populations to identify therapeutically effective compounds against such diseases. As several non-limiting examples, it is known in the art that the population of Tristan de Cunha has **an increased prevalence of asthma**, as described in Zamel et al., Am. J. Respir. Crit. Care Med. 153:1902-1906 (1996); that the Pima Indians have an **increased frequency of non-insulin dependent diabetes** mellitus, as described in Bogardus et al., J. Cell Biochem. 48:337-343 (1992); that the population of Finnish North Karelia has **an increased incidence of hypercholesteremia and coronary heart disease**, as described in Vuorio et al., Arterioscler. Thromb. Vasc. Biol. 17:3127-3138 (1997); and that the population of the Central Valley of Costa Rica **has increased prevalence of bipolar disorder**, as described in Sheffield et al., Trends in Genetics 14:391-396 (1998). [emphasis added] (col. 6, lines 17-36)

This paragraph simply **does not** teach a method involving calculating an incidence of disease, and certainly not within a subfamily determined within a computerized genealogical database are recited in pending claim 1. This paragraph **does not** teach "presenting a measure of said statistical significance on a display or printout" as recited in claim 1.

In view of the foregoing, Palsson (U.S. Patent 6,524,797) does not teach all of the elements of the presently claimed method. Accordingly, the rejection under 35 U.S.C. §102(b) should be withdrawn.

Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 267-4161.

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Respectfully submitted,

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